REMARKS

Status of the Claims.

Claims 1-4, 6-10, 20-29, and 31 are pending with entry of this amendment, claims 5, 11-19, and 30 being cancelled and no claims being added herein. Claims 1 and 3 are amended herein. These amendments introduce no new matter. Support is replete throughout the specification (*e.g.,*).

35 U.S.C. §112, Second Paragraph.

Claims 1-12 were rejected under 35 U.S.C. §112, second paragraph, as allegedly indefinite because the claim allegedly did not recite "effective amounts of a gastric proton pump inhibitor and a pentagastrin, a gastrin, or a gastrin analogue. Claim 1 is amended herein to recite ". . . **an effective amount** of one or more agents selected from the group consisting of a pentagastrin, a gastrin, and a gastrin analogue" thereby obviating this rejection.

It is not necessary to recite an effective amount of a proton pump inhibitor, because the claim is directed to increasing the efficient of any amount of proton pump inhibitor.

35 U.S.C. §112, First Paragraph.

Claims 1-12, 20-29, and 31 were rejected under 35 U.S.C. §112, first paragraph. In particular, the Examiner alleged that the specification does not reasonably provide enablement for a method of increasing the efficacy of a PPI in a mammal by administering gastrin or an analog of gastrin or pentagastrin with a PPI for the treatment of pathology of excess gastric acid secretion (*see, e.g.,* Office action, page 3). In support of her argument, the Examiner alleged that ". . . the specification, however, only discloses cursory conclusions without data supporting the findings . . . ". (*see,* Office Action, page 3, paragraph 2).

Applicants first note that the Examiner's allegation that the claims are not enabled because the specification fails to provide sufficient supporting data, is improper. Applicants have provided objective evidence that pentagastrin increases the efficacy of a typical PPI. The Examiner has offered no objective evidence to suggest that pentagastrin, gastrin, or gastrin analogues would fail to function in a similar manner with other PPIs and has therefore failed to make her *prima facie* case.

Moreover with respect to the scope of gastrin analogues and PPIs, the Examiner is reminded that to be enabling under §112, first paragraph, a patent must contain a description that enables one skilled in the art to make and use the claimed invention. **That some experimentation is**

necessary does not constitute a lack of enablement; the amount of experimentation, however, must not be unduly extensive.

Whether undue experimentation is required by one skilled in the art is typically determined by reference to eight factors considered relevant to the inquiry: (1) quantity of experimentation necessary; (2) amount of guidance presented; (3) presence of working examples; (4) nature of the invention; (5) state of the prior art; (6) relative skill of those in the art; (7) predictability of the art; and (8) breadth of the claims. *In re Wands,* 8 USPQ2d 1400 (Fed. Cir. 1988) *citing Ex parte Forman Inc.,* 230 USPQ 546 (BPAI 1986).

In the instant case, many PPIs are known to those of skill in the art (*see, e.g.,* specification pages 8-9). In addition, with respect to gastrin analogues, the specification expressly teaches that gastrin analogues ". . . that stimulate endogenous gastrin secretion or that generally stimulate G-cell activity will be useful in the methods of this invention.." (*see, e.g.,* Specification page 10, lines 1-25).

With respect to the "Wands" factors, Applicants note that the quantity of experimentation (Wands Factor 1) is modest. PPIs are readily screened in conjunction with gastrin or gastrin analogues. Considerably guidance is provided in the specification (Wands Factor 2). In particular specific gastrin analogues and PPIs are identified. Working examples (Wands Factor 3) are provided. The nature the invention (Wands Factor 4) is relatively straightforward pertaining to the increase in efficiency of PPIs using gastrin pentagastrin or gastrin analogues. The state of the prior art (Wands Factor 5) is well developed. PPIs and gastrin analogues are well known to those of skill in the art. The relative skill of those in the art (Wands Factor 6) is high, typically Ph.D. The predictability of the art is high Wands Factor (7). PPIs act by similar mechanism(s) as do gastrin, pentagastrin and gastrin analogues. In addition, contrary to the Examiner's assertion, the claims are not extremely broad (Wands Factor 8) being directed simply to the combined use of PPIs (a relatively uniform group of compounds) and pentagastrin, gastrin, or gastrin analogues. Thus, when analyzed in light of In re Wands, practice of claims 1-12, 20-29, and 31 does not require undue experimentation and the rejection of these claims under 35 U.S.C. §112, first paragraph, should be withdrawn.

35 U.S.C. §102.

Claims 1, 2, 5, 6, and 7 were rejected under 35 U.S.C. §102(b) as allegedly anticipated by Simon *et al.* (199) *Aliment Pharamacol Therap.*, 4: 239-245. Claims 1 and 12 were rejected under 35 U.S.C. §102(b) as allegedly anticipated by Murphy *et al.* (U.S. Patent 4,997,950). Applicants respectfully traverse.

A) Simon *et al.*

The present invention pertains to the surprising discovery that administration of a pentagastrin, gastrin, or gastrin analogue can increase the efficiency of a gastric H+/K+-ATPase pump inhibitor (PPI). Reflecting this discovery, claim 1, as amended herein recites:

> 1. A method of increasing the efficacy of a gastric H+/K+-ATPase pump inhibitor (PPI) in **a human in need of a PPI**, said method comprising:
> administering to said human an effective amount of one or more agents selected from the group consisting of a pentagastrin, a gastrin, and a gastrin analogue, in conjunction with said gastric proton pump inhibitor whereby the efficiency of said gastric proton pump inhibitor is increased.

In contrast, the test subjects described by Simon *et al.* are **healthy male volunteers** (*see, e.g.*, abstract, line 1). In this study, pentagastrin was administered to the **healthy subjects** to increase gastric acid secretion so that it became possible to test the effects of the PPI (BY 1023/SK7F 96022).

In other words, the pentagastrin was administered to healthy volunteers to induce a "pathological state" for the purpose of testing a PPI. There is nothing in Simon *et al.* that would lead one of skill to realize that the pentagastrin had any beneficial effect in the treatment of an already existing pathological condition characterized by excess acid secretion.

Simon *et al.* thus simply fails to teach or otherwise disclose the administration of pentagastrin, gastrin, or a gastrin analogue **to a human in need of a PPI for the purpose of increasing the efficiency of the PPI**. Accordingly, Simon *et al.* fails to anticipate claims 1, 2, 5, 6, or 7 and the rejection under 35 U.S.C. §102(b) in light of Simon *et al.* should be withdrawn.

B) Murphy *et al.*

Claims 1 and 12 were rejected under 35 U.S.C. §102(b) as allegedly anticipated by Murphy *et al.* (U.S. Patent 4,997,950). Applicants respectfully traverse.

The Examiner is respectfully reminded that "[a] claim is anticipated only if **each and every element as set forth in the claim** is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. V. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

In the instant case, Murphy *et al.* describes the administration of derivatives of the C-terminus of gastrin to **dogs** ". . . to study the structure of the molecule and also to determine the smallest and highest affinity inhibitor of gastrin." (*see, e.g.,* Abstract).

In contrast, claim 1, as amended herein is directed to "[a] method of increasing the efficacy of a gastric H+/K+-ATPase pump inhibitor (PPI) in **a human in need of a PPI**, . . . ". Murphy *et al.* fails to teach or otherwise disclose the administration of a PPI and a pentagastrin, gastrin, or gastrin analogue to a **human**. Murphy *et al.* thus fails to provide all the elements of claim 1 and therefore fails to anticipate that claim. Thus, the rejection of claim 1 under 35 U.S.C. §102(b) in light of Murphy *et al.* should be withdrawn. Claim 12 is canceled thereby obviating the rejection of that claim.

In view of the foregoing, Applicants believes all claims now pending in this application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested. Should the Examiner seek to maintain the rejections, Applicants request a telephone interview with the Examiner and the Examiner's supervisor.

If a telephone conference would expedite prosecution of this application, the Examiner is invited to telephone the undersigned at (510) 769-3513.

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Respectfully submitted,

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